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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,571	04/07/2005	Nathali Bosc	MERCK-2992	8984

23599 7590 10/11/2007  
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EXAMINER

RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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10/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/530,571	BOSC ET AL.	
	Examiner	Art Unit	
	Niloofer Rahmani	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 3-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1, 3-15 are currently pending in the instant application and claim 2 is cancelled.

#### *Priority*

2. This application is filed on 04/07/2005, which is a 371 of PCT/EP03/09680, filed on 09/01/2003, which claims benefit of FRANCE 02/12432, filed on 10/07/2002. The claimed benefit of priority date is denied. There is no certified translation of the priority document. The filing date of the instant application is 09/01/2003.
3. The rejection of claim 14 under 35 U.S.C. 101 and 35 U.S.C. 112, second paragraph for the use of compounds is withdrawn in view of the applicant's amendment on paper dated on 08/06/2007.
4. The rejection of claims 3-12, and 15 under 35 U.S.C. 112, second paragraph is maintained for reason of record. Applicants argue that the term "salifying" is amended by the "forming a carboxylic acid salt of". It is examiner's position that step (a) does not have any steps. There is no step to form carboxylic acid salt of Formula (I) from another compounds. Applicants also argue that the term "acidifying" is manifestly unambiguous to one ordinary skill in the art. It is examiner's position that step (b) does not have any steps. The production from the step (a) is the salt(dry or powder). Therefore, in step (b), the term "acidifying an aqueous solution from the step (a)" is not correct.

The production from the step (a) is not aqueous solution; it is salt, which is powder and dry.

5. The rejection of claims 13-14 under 35 U.S.C. 102(b) over Brunet et al., WO 00/39113 is maintained for reason of record. Applicants argue that the present claim 1 is a "metastable form" of formula (I). It is examiner's position that claim 13 is a "pharmaceutical composition of the formula (I)". Therefore, claim 13 is aqueous and is water solution. Claim 14 is the use of the "pharmaceutical composition of the formula (I)", which is anticipated.

6. The rejection of claims 13-14 under 35 U.S.C. 102(e) over Brunet et al., US 6,596,758 is maintained for reason of record. Applicants argue that the present claim 1 is a "metastable form" of formula (I). It is examiner's position that claim 13 is a "pharmaceutical composition of the formula (I)". Therefore, claim 13 is aqueous and is water solution. Claim 14 is the use of the "pharmaceutical composition of the formula (I)", which is anticipated.

7. The rejection of claims 13-14 under provisionally Obvious-Type Double Patenting over Brunet et al., US 6,596,758 is maintained for reason of record. Applicants argue that the present claim 1 is a "metastable form" of formula (I). It is examiner's position that claim 13 is a "pharmaceutical composition of the formula (I)". Therefore, claim 13 is aqueous and is water solution. Claim 14 is the use of the "pharmaceutical composition of the formula (I)", which is anticipated.

8. ***Allowable Subject Matter***

Claim 1 is patentable over Brunet et al., WO 00/39113. The reference does not teach the specific metastable form of a compound of formula (I) in claim 1. Therefore, the claim 1 is free of prior art.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

10/09/2007

NR

  
D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625